The budget is over! Is reuse of devices feasible?

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Bucharest, ROMANIA

Arrhythmias Update 2017
April 7-8th
Thessaloniki, Greece
CEID reuse - Background

- 1-2 million people/year worldwide die due to lack of access to PM/ICDs
- 80% of CVD death take place in LMICs
- Thousands of PM/ICDs as life saving devices are thrown away or buried with a body (following up-grades/death of pt)
- 84% of explanted devices are discarded as medical waste
- 42% as stored devices in a box in EP labs
- Few CEID are donated to charity for use overseas

NB - How many CEID are destroyed close to expiration/sterility date?
Sources of donated devices –

- **Up-grades** – from PM to ICD, ICD to CRT-D...
- **Infected devices** – rate of device infection -0.13- 2(3)% - mean time between implant and explant less than 162 days
- **Postmortem** (the largest source of CEID)
  - Pts over 80 y of age reprezent 32% of PM implants and growing
  - mortality at 4 y from implant is over 40%, so Battery life expectancy is more than 5 y
  - CEID must be remove prior to cremation (to prevent explosion)
Is Cardiac Electronic Implantable Devices (CEID) reuse feasible?

- Medical issues
- Legal issues
- Ethical and cultural issues
- Economical issues
- Our experience in Romania
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### PM implant rate

<table>
<thead>
<tr>
<th>Location</th>
<th>PM Implant Rate</th>
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<tbody>
<tr>
<td><strong>Europe</strong></td>
<td>up to <strong>1000</strong> PM/1 mil people/y</td>
</tr>
<tr>
<td><strong>USA</strong></td>
<td><strong>752</strong> PM/1 mil/y</td>
</tr>
<tr>
<td><strong>Thailand</strong></td>
<td><strong>22</strong> PM/1 mil/y</td>
</tr>
<tr>
<td><strong>Peru</strong></td>
<td><strong>14</strong> PM/1 mil/y</td>
</tr>
<tr>
<td><strong>Bangladesh</strong></td>
<td><strong>4</strong> PM/1 mil/y</td>
</tr>
</tbody>
</table>

* at present countries as Belgium, Germany = 1200 PM/1 mil/y
Is CEID reuse feasible?  
Medical & Logistical issues

- Need for a PM/ICD/CRT living will? filled out by pts at the time of implantation? Family options?
- Potential to transmit infections? Checking for battery longevity and removal of recorded donor data
- at Present – Manufacturers of CEID recommend single use!
- Cleaning (removal of all protein material- plastic components1), Recalibration (screw set!), Sterilisation, Transporting...
Current rate of device extraction in S-E Michigan funeral homes


Circulation, 2010
Whay people think about using pacemakers postmortem? Views of general population and patients with PM/ICDs relative to device reuse

![Bar chart showing percentage in favor of device reuse](image)

T. Barman, J. Kirkpatrick, H. Oral, ... K. Eagle

*American Heart Association*

*Circulation 2010, 122, 1649-1656*
Organizations involved with initiative of re-using pacemakers

- Heart too Heart Aid (www.hearttoheart.org)
- Solidarity Bridge (www.solidaritybridge.org)
- University of Michigan-Project My Heart is Your Heart (www.myheartisyourheart.org)
- Heartbeat International –Florida, USA (www.heartbeatinternational.org)
- World Medical Relief- Detroit, Michigan, USA (www.worldmedicalrelief.org)
- Alternative Solution www.alternativesolution.org
- For Nicaraguan Health, Rotary International
Project My Heart – Your Heart – a collaboration between pts, physicians, non-profit organisations and funeral homes to collect and donate CEID

Baman et al., Circulation 2010, 122,1649-1656
Reused CEID – potential to transmit infections? A main concern?

- FDA* - there is a serious question whether PMs can be properly re-sterilized following initial implantation due to possibility of body fluid entering the terminal leads of PM

- Multiple studies have demonstrated that there is no increased rate of infection
  - Sweden (C. Linde-Eur Heart J 1998), -
  - Canada (M. Rosengarten-Can J Cardiol 1989,
  - USA (Kirkpatrick, J Cardiovasc Electrophysiology 2007
  - France (J. Mugica – Pacing Clin Electrophysiology on Survival and mortality on 3,701 PM – arguments in favor of pacemaker reuse

- New leads in all reused CEID implants
Is Cardiac Electronic Implantable Devices (CEID) reuse feasible?

- Medical issues
- **Legal issues**
- Ethical and cultural issues
- Economical issues
- Our experience in Romania
CEID reuse - Legal issues

- Reused PM/ICD - Ownership -? Implanting center?, Private pt?, Insurer ?, government?
- PM/ICD pts explant and donate living will ?
- Liability and warranty of explanted device?
- Responsibility for – reporting, registration, validation, listing, explant/re-implant device interrogating/labeling, transporting/export, complications ,
- Unlikely the manufacturers could be implicated in reused device malfunction, early battery depletion, ?? Next device replacement?
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Ethical issues – of potential reuse CEID-to be sorted out!

- Psychological benefit of device donation for family members vs public interest
- Explanted and donated vs explanted and return to manufacturers for analysis and future device improvements
- Create a LMIC black market for re-used devices vs fair distribution of medical resources
- Donated CEID – contribution to medical training for local implanting doctors
- Tracking device vs private new recipient pt data
- Reused ICDs for primary vs secondary SD prevention
- Is LMIC able to afford the new leads cost?
- Local cultural/tradition/religious issues for reused devices?
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Reuse of CEID – Economical issues

- What is the cost of devices into the total cost of PM/ICD patient care!
- The cost of reuse process of explanted devices prior to reimplantation
- Cost of the new leads
- Cost of follow ups
Economical issues of reused CEID

Cost-of-illness study of patients subjected to cardiac rhythm management devices implantation - results from a single tertiary centre

John Fanourgiakis, Emmanuel Simantrirakis, Nikolaos Maniadakis, Georgia Kourlaba, Emmanual Kanoupakis, Stavros Chrysostomakis, and Panos Vardas

Heraklion Univ Hospital, Crete, Greece

Europace (2013) 15, 366-375
From *Cost-of-illness study of patients subjected to cardiac rhythm management devices implantation: results from a single tertiary centre*


Figure Legend:
Percentage of total cost attributed to each type of cost.
From *Cost-of-illness study of patients subjected to cardiac rhythm management devices implantation: results from a single tertiary centre*


Figure Legend:
Percentage of total annual direct health care cost attributed to each source.
PM/ICD implantation cost

- PM initial total cost implant (euro) - 3926
- PM mean procedure cost (device, suppliers, personnel time) - 1803 (44.6% of total)
- PM annual F-up cost (euro) - 1816
- ICD initial total cost implant (euro) - 17764
- ICD mean procedure cost (euro) - 13521 (76% of total)
- ICD annual F-up cost (euro) - 2819

ADD medication, investigation, image procedure during rehospitalization, replacements.

J. Fanourgiakis, P. Vardas, Europace 2013, 15, 366-375

COST – EFFECTIVENESS OF RE-USED CEID LOOKS RELIABLE AS DEVICE COST IS 50-75% OF TOTAL COST OF HEALTHCARE OF PTS WITH IMPLANTABLE DEVICES (resterilization process is around 75-100 USD). The more sophisticated device the most cost-effective is the reuse.
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ROMANIA
Location: Eastern Europe
EU member since Jan 2007
Population: 22.5 mil
7th largest country in EU

Capital:
   Bucharest, 2.6 mil
Until 2013 – aprox 130 PM/1 mil/y
   aprox 5-10 ICD/1mil/y
following MS/CNAS programmes
Present (Bucharest area):
   aprox 400 PM/1 mil/y
   aprox 100 ICD/1mil/y
All large tertiary centers had some experience in reusing PM/ICDs before 2013

Timisoara -( West part of Romania) has the largest experience— collaboration with non-profit organisations from France

Bucharest – collaboration with a foundation from USA
Timisoara reuse CEID experience – a retrospective study*

- The aim of the study was to present our experience regarding the safety of re-used implantable devices compared with the new devices.
- Implantable devices: pacemakers and ICD’s.
- Retrospective study 2001-2011 for the consecutive patients implanted in our hospital with new and reused devices.

* courtesy of Prof S. Pescariu – head of Cardiology Institute in Timisoara
Materials and methods

- Retrospective study:
  - 3877 patients implanted between January 2001 and December 2010
  - 2732 (70.46%) patients implanted with new devices, (single, dual, triple chamber PM and ICD)
  - 1145 (29.54%) implanted with reused devices (single, dual, triple chamber PM and ICD)
1. PM. Reutilizations criteria

1. No signs of malfunction detected during first implantation
2. Physical integrity after explantation
3. Normal parameters detected at PM control
4. First implantation performed in the last twelve months
5. Estimated life expectancy of implantable device >2/3 of theoretical life expectancy
PM. Resterilization method

› Washed with water and soap
› Checked for external damage
› Controlled with adequate programmer for impedance and battery longevity assessment
› Resetting device to its original settings

› 12 h immersion in cocospropyldiaminoguanidiniumdiacetate/didecyl methyloxethyammoniumpropionate
› Second wash with 70% ethanol

› Ethylene oxide sterilization after packaging and labeling with first implantation date and programmed parameters values
The patients was informed all the time concerning the condition of the device.

The choice between new and reused CEID was the impossibility to obtain in time a new adequate device for a patient with symptomatic bradycardia (PM) or symptomatic heart failure (for CRT devices).
PM. Conditions at implantation of the reused PMs

- Similar with the new PMs!

- The leads implanted are news!

- Antibiotic prophylaxis consisting in iv amoxycilin/clavulanat 30 minutes before intervention for all patients
PM. Considered complications

- Two complications were considered:
  1. Infection
     a) Subcutaneous pocket infections requiring antibiotherapy or reintervention.
     b) Lead related endocarditis.
  2. Device malfunction requiring premature replacement < 1 year.
     a) Premature battery depletion
     b) Connection abnormality
PM. Follow up

- Patients were periodically evaluated during follow-up as for new device implantation
## PM-RESULTS

<table>
<thead>
<tr>
<th>Pacemakers</th>
<th>New PM 2705</th>
<th>Reused PM 1033</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total 3738</td>
<td>(72.44%)</td>
<td>(27.56%)</td>
</tr>
<tr>
<td>Women</td>
<td>1127</td>
<td>397</td>
</tr>
<tr>
<td></td>
<td>74%</td>
<td>26%</td>
</tr>
<tr>
<td>Man</td>
<td>1578</td>
<td>636</td>
</tr>
<tr>
<td></td>
<td>71%</td>
<td>29%</td>
</tr>
<tr>
<td>Age±STD</td>
<td>67.89±12.02</td>
<td>70.75±9.19</td>
</tr>
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</table>
More advance PMs – higher % of reused devices

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Total 3738</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-chamber PM</td>
<td>1762 79.01%</td>
<td>468 20.98%</td>
</tr>
<tr>
<td>Dual chamber PM</td>
<td>826 62.43%</td>
<td>497 37.56%</td>
</tr>
<tr>
<td>Triple chamber PM</td>
<td>117 63.24%</td>
<td>68 36.75%</td>
</tr>
<tr>
<td>Device</td>
<td>Infection</td>
<td>malfunction</td>
</tr>
<tr>
<td>---------</td>
<td>-----------</td>
<td>-------------</td>
</tr>
<tr>
<td>New</td>
<td>28</td>
<td>0</td>
</tr>
<tr>
<td>Reused</td>
<td>21</td>
<td>2</td>
</tr>
</tbody>
</table>
2. ICD Reutilizations criteria

1. No signs of malfunction detected during first implantation
2. Physical integrity after explantation
3. Normal parameters detected at ICD control remaining longevity more than 70% proved at interrogation of ICD, analyzing the programmed bradycardia pacing parameters, the percentage of paced to sensed events, the pacing load, and the frequency of high voltage capacitor charging
4. Same resterilization algorithm
5. Same type of consent forms as for PM
6. Same antibiotic prevention therapy preimplant
7. New leads
**ICDs-RESULTS**

<table>
<thead>
<tr>
<th>ICDs</th>
<th>New ICD 64 (34.56%)</th>
<th>Reused ICD 121 (65.44%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total 185</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-chamber ICD</td>
<td>49</td>
<td>54</td>
</tr>
<tr>
<td></td>
<td>76.56%</td>
<td>44.63%</td>
</tr>
<tr>
<td>Dual chamber ICD</td>
<td>10</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>15.63%</td>
<td>26.45%</td>
</tr>
<tr>
<td>Triple chamber ICD</td>
<td>5</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>7.81%</td>
<td>28.93%</td>
</tr>
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The implantation of re-used devices can be performed without increased risk to the patients provided with proper routine for technical control and sterilization.

This is a live saving solution in areas with poor health care services but with correct knowledge of medical procedures for implantation and follow-up.
ROMANIA REPORT at 24th Annual HEARTBEAT International Arrhythmia Workshop – Orlando, FL

HBI BUCHAREST Bank ROMANIA

The Old Court Rotary Club Bucharest - ROMANIA

March 27, 2009
Rotary Club in ROMANIA

Rotary Club since early 1920-1939
Rotary Club since 1992
The Old Court Rotary Club Bucharest since 1998
District 2241 Romania and Rep.of Moldova since 2001

HeartBeat International Bucharest Bank 1994-2009
Bucharest CEID close to expire implanting experience
15 years of HeartBeat International Bucharest Bank in Romania
1994-2009
Bucharest Bank - a member of HBI great family

ARGENTINA, BUENOS AIRES
BARBADOS, ST. MICHAEL
BOLIVIA, SANTA CRUZ
CHILE, LA SERENA
CHILE, SANTIAGO
CHILE, VINA DEL MAR
CHINA, CHENGDU PRC
COLOMBIA, BOGOTA
COLOMBIA, MEDELLIN
COSTA RICA, SAN JOSE
ECUADOR, QUITO
EL SALVADOR, SAN SALVADOR
GUATEMALA, GUATEMALA CITY
HONDURAS, TEGUCIGALPA
INDIA, BANGALORE
INDIA, CHANDIGARH
INDIA, HYDERABAD
INDIA, JAMSHEDPUR
INDIA, KANPUR
INDIA, KERALA
INDIA, LUDHIANA
INDIA, NEW DELHI
INDIA, PATNA
ISRAEL, JERUSALEM
JAMAICA, KINGSTON
KENYA, NAIROBI
KAUNAS, LITHUANIA
MALAYSIA, PENANG
MEXICO, AGUASCALIENTES
MEXICO, GUADALAJARA
MEXICO, MEXICO CITY
MEXICO, MONTERREY
MEXICO, PUEBLA
MEXICO, VILLAHERMOSA
PANAMA, PANAMA CITY
PERU, LIMA
PHILIPPINES, LIPA CITY
ROMANIA, BUCHAREST
RUSSIA, TOMSK
SURINAME, PARAMARIBO
THAILAND, CHIANG MIA
TRINIDAD, ST. AUGUSTINE
VENEZUELA, VALENCIA
VENEZUELA, MARACAIBO
HBI Bucharest Bank pays tribute to HBI Founder Dr. Henry McIntosh
Former President of the American College of Cardiology
Institute of CV Diseases
Bucharest

2016 – close to 900 CEID implants/year

- 336 beds
- 4 Cardiology Depts
- Coronary Care Unit
- 2 Cardiac Surgery Depts
- Vascular Surgery Dept
- Cardiac Cateterisation Dept
- Arrhythmia, Cardiac electrophysiology and Pacing Dept (2 Labs)
- 2 Intensive Care Depts
- Echo Labs
- Out Patients Dept
BUCHAREST CEID close to expire date implantation experience

Our HeartBeat International Patients

HBI Bucharest Bank
114 devices with a relative value of 456 000 euros
local Rotary Club in Bucharest supervised the charity activity
P.G. 1 y and 9 month, Congenital 3\textsuperscript{rd} degree AV B, ?DCMP

Epicardial LV lead, HBI pacemaker 2006, good evolution at 18 months since the PM implant
LV epicardial lead
Bucharest Bank
Our patients

Saying thank you to HeartBeat International and Rotary Club
“From the bottom of my heart thank you to HBI Foundation and to Rotary Club Bucharest for giving me the chance to live a second life”
Implanting an HBI pacemaker donation to a 67 y old recipient
HBI PM recipient since 2002
“... I will pray for the HBI Foundation and for the people who are running The Foundation”
“I have my HBI PM for 7 years now. Before I could do no more than to sit down. Now I can do again my job do to a very performant pacemaker I received from HBI; even I’ve been climbing the hundreds of stairs at St. Pietro Cathedral in Rome to pray for you and your Foundation…”
CONCLUSIONS

- Pacemakers and CEID reutilization can be effectively and safely done and does not pose significant risk to the recipients.
- Heart pts with reused PM and other CEID have an improved life compared to those without implanted devices – and CEID reutilization is a life-saving initiative.
- CEID is cost effective.
- Consistent with the principle of justice used CEID with adequate battery life and properly sterilized should be used for pts who cannot afford the cost of a new device.
- The legal and organisational environment to reuse CEID is not yet prepared for large scale of reusing implantable devices and still needs in depth analysis and decisions.
Romania - Peles Royal Castle in Sinaia town

SINAIA name comes from Mount Sinai

Thank you!